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*Attorneys for Defendant Accord Healthcare Inc.*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

AMERICAN REGENT, INC.,

*Plaintiff,*

v.

ACCORD HEALTHCARE INC.,

*Defendant.*

Civil Action No. 24-7791

**DEFENDANT ACCORD HEALTHCARE INC.'S ANSWER TO PLAINTIFF'S  
COMPLAINT WITH AFFIRMATIVE DEFENSES AND COUNTERCLAIMS**

Defendant Accord Healthcare Inc. ("Accord"), through its attorneys, hereby answers the Complaint of Plaintiff American Regent, Inc. ("American Regent" or "Plaintiff") and asserts affirmative defenses and counterclaims as follows:

**NATURE OF THE ACTION**

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, arising from Accord's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application No. 218655 ("the ANDA") which contains a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certification") seeking approval to engage in the commercial manufacture, use, sale, and/or importation of generic versions of ART's Selenious

Acid products (the “ANDA Products”) prior to the expiration of United States Patent No. 11,998,565 (“the ‘565 patent”).

**ANSWER:** Accord admits that Plaintiff’s Complaint purports to set forth an action for patent infringement under the patent laws of the United States, Title 35 U.S.C. § 100 *et seq.* Accord admits that Accord Healthcare Inc. submitted ANDA No. 218655 to FDA seeking approval for Selenious Acid Injection USP, 60 mcg base/mL single-dose vials; 600 mcg base/10 mL (60 mcg base/mL) Pharmacy Bulk Package (“Proposed ANDA Products”). Accord admits that ANDA No. 218655 contains a Paragraph IV Certification as to United States Patent No. 11,998,565 (“the ‘565 patent”). Accord denies any remaining allegations in Paragraph 1.

### **THE PARTIES**

2. ARI is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

**ANSWER:** Accord lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 2, and therefore denies them.

3. On information and belief, Accord is an American corporation organized and existing under the laws of North Carolina with its principal place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

**ANSWER:** Accord admits that Accord Healthcare Inc. is a corporation organized and existing under the laws of North Carolina. Accord denies the remaining allegations in Paragraph 3.

### **JURISDICTION AND VENUE**

4. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

**ANSWER:** Paragraph 4 contains legal conclusions to which no response is required. To the extent a response is required, Accord admits that Plaintiff’s Complaint purports to set forth an action for patent infringement under 35 U.S.C. § § 100 *et. seq.* Accord admits that this Court has

subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a) for claims under 35 U.S.C. § 271(e) relating to ANDA No. 218655 only. Accord denies any remaining allegations in Paragraph 4.

5. On information and belief, this Court has personal jurisdiction over Accord, under the New Jersey state long arm statute and consistent with due process of law because Accord has extensive contacts with the State of New Jersey and regularly does business in this judicial district. Further, Accord plans to sell its ANDA Products in the State of New Jersey, which provides an independent basis for personal jurisdiction here.

**ANSWER:** Paragraph 5 contains legal conclusions to which no response is required. To the extent a response is required, denied. Accord does not contest personal jurisdiction for the purposes of this action only.

6. This Court has personal jurisdiction over Accord because Accord has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contact with the State of New Jersey. On information and belief, Accord regularly and continuously transacts business within New Jersey, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey. On information and belief, Accord derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. On information and belief, Accord derives substantial revenue from selling generic pharmaceutical products and/or pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this judicial district.

**ANSWER:** Paragraph 6 contains legal conclusions to which no response is required. To the extent a response is required, denied. Accord does not contest personal jurisdiction for the purposes of this action only.

7. This Court has personal jurisdiction over Accord because, on information and belief, Accord derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this judicial district.

**ANSWER:** Paragraph 7 contains legal conclusions to which no response is required. To the extent a response is required, denied. Accord does not contest personal jurisdiction for the purposes of this action only.

8. On information and belief, Accord is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this judicial district.

**ANSWER:** Accord admits that it is in the business of marketing, offering for sale and selling pharmaceutical products in the United States. Accord denies any remaining allegations in Paragraph 8. Accord does not contest personal jurisdiction for the purposes of this action only.

9. On information and belief, Accord intends to benefit directly if the ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the ANDA Products.

**ANSWER:** Accord admits that Accord's ANDA No. 218655 seeks approval to engage in the manufacture, importation, distribution, and/or sale of the Proposed ANDA Products. Accord lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 9, and therefore denies them. Accord does not contest personal jurisdiction for the purposes of this action only.

10. On information and belief, this judicial district will be a destination for the generic drug products described in the ANDA.

**ANSWER:** Accord lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 10, and therefore denies them. Accord does not contest personal jurisdiction for the purposes of this action only.

11. On information and belief, Accord regularly and continuously transacts business within New Jersey, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey.

**ANSWER:** Accord admits that Accord Healthcare Inc. has sought approval for the marketing and sale of certain drug products in the United States. Accord denies any remaining allegations in Paragraph 11. Accord does not contest personal jurisdiction for the purposes of this action only.

12. This Court has personal jurisdiction over Accord because, inter alia, Accord has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course

of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to ARI in New Jersey. Further, on information and belief, following approval of the ANDA, Accord will make, use, import, sell, and/or offer for sale the ANDA Products in the United State, including in New Jersey, prior to the expiration of the '565 patent.

**ANSWER:** Paragraph 12 contains legal conclusions to which no response is required. To the extent a response is required, denied. Accord does not contest personal jurisdiction for the purposes of this action only.

13. On information and belief, Accord has previously been sued in this Judicial District and has not challenged personal jurisdiction. Accord has also availed itself of New Jersey courts through the assertion of counterclaims in suits brought in New Jersey. *See, e.g., Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialties Limited et al.*, C.A. No. 23-00926, Dkt. 48 (D.N.J. Oct. 28, 2022); *Janssen Pharmaceuticals, Inc. et al. v. Accord Healthcare Inc. et al.*, C.A. No. 22-00856, Dkt. 5 (D.N.J. Feb. 18, 2022); *Eagle Pharmaceuticals, Inc. et al. v. Accord Healthcare Inc.*, C.A. No. 19-09031, Dkt. 11 (D.N.J. Apr. 15, 2019).

**ANSWER:** Paragraph 13 contains legal conclusions to which no response is required. To the extent a response is required, Accord admits that it is a party to the cases identified in Paragraph 13 and asserted counterclaims in some of the cases identified in Paragraph 13. Accord denies any remaining allegations in Paragraph 13. Accord does not contest personal jurisdiction for the purposes of this action only.

14. Venue is further proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

**ANSWER:** Paragraph 14 contains legal conclusions to which no response is required. Accord does not contest venue for the purposes of this action only.

15. Venue is proper for Accord under 28 U.S.C. §§ 1391 and/or 1400(b). On information and belief, Accord has committed and will commit further acts of infringement in this judicial district. In addition, Accord does business in this judicial district through a permanent and continuous presence in the State of New Jersey. For example, Accord is registered with the State of New Jersey's Department of Health as a drug manufacturer under Registration No. 5003815 and continuously sells its products in this judicial district. Upon information and belief, Accord employs a sales force that includes personnel that regularly and continuously work in this judicial

district and, if Accord succeeds in obtaining FDA approval of the ANDA, Accord will use its salesforce to sell the ANDA Products in the State of New Jersey.

**ANSWER:** Paragraph 15 contains legal conclusions to which no response is required. To the extent a response is required, Accord admits that it is registered with the State of New Jersey's Department of Health as a drug manufacturer under Registration No. 5003815. Accord admits that it continuously sells its products in this judicial district. Accord admits that it employs a sales force that includes personnel that call on accounts located in this judicial district. Accord denies the remaining allegations in Paragraph 15. Accord does not contest personal jurisdiction for the purposes of this action only.

16. In an email correspondence dated July 10, 2024, Accord consented to personal jurisdiction and venue in the District of New Jersey for purposes of this case.

**ANSWER:** Admitted.

### **BACKGROUND**

17. ARI holds New Drug Application ("NDA") No. 209379 for Selenious Acid ((1) eq. 600 mcg Selenium/10mL (eq. 60 mcg Selenium/mL), (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL), and (3) eq. 12 mcg Selenium/2 (eq. 6 mcg selenium/mL)), which was originally approved by the FDA on April 30, 2019, which ARI manufactures and sells in this judicial district and throughout the United States.

**ANSWER:** Accord admits that the Orange Book states that ARI is the holder of NDA No. 209379. Accord admits that the Orange Book states that Selenious Acid eq. 600 mcg Selenium/10mL (eq. 60 mcg Selenium/mL) was originally approved by FDA on April 30, 2019. Accord lacks information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 17, and therefore denies them.

18. ARI's Selenious Acid products are covered by one or more claims of the '565 patent.

**ANSWER:** Accord lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 18, and therefore denies them.

19. ARI is the owner of the '565 Patent, entitled "Trace element compositions, methods of making and use," which was duly and legally issued on June 4, 2024. A copy of the '565 patent is attached as Exhibit 1.

**ANSWER:** Accord admits that the '565 patent is entitled "Trace Element Compositions, Methods of Making and Use" and that it issued on June 4, 2024. Accord admits that Exhibit 1 attached to the Complaint appears to be a copy of the '565 patent. Accord denies that the '565 patent was duly and legally issued. Accord admits that ARI purports to be the owner of the '565 patent. Accord denies any remaining allegations in Paragraph 19.

20. The '565 patent has been listed in connection with ARI's Selenious Acid products in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book").

**ANSWER:** Admitted.

21. As indicated in the Orange Book, the patent expiration date for the '565 patent is July 1, 2041.

**ANSWER:** Accord admits that the Orange Book indicates that the patent expiration date for the '565 patent is July 1, 2041. Accord lacks information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 21, and therefore denies them.

22. On information and belief, Accord was responsible for preparing the ANDA which contained a Paragraph IV Certification.

**ANSWER:** Admitted.

23. By letters dated June 11, 2024 ("the Notice Letters"), Accord notified ARI pursuant to the Federal Food, Drug, and Cosmetic Act that Accord had each submitted to the FDA the ANDA with a Paragraph IV Certification to seek approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Products prior to the expiration of the '565 patent.

**ANSWER:** Accord admits that it sent a letter to Plaintiff on or about June 11, 2024, regarding the submission of ANDA No. 218655 and its subsequent Paragraph IV Certification to FDA seeking approval for the Proposed ANDA Products prior to the expiration of the '565 patent. Accord denies any remaining allegations in Paragraph 23.

24. On information and belief, Accord submitted the ANDA to the FDA, which contained a Paragraph IV Certification asserting that the '565 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of the ANDA Products, or alternatively, that the '565 patent is invalid.

**ANSWER:** Admitted.

25. The Notice Letter contained no non-infringement defenses for any claim of the '565 patent.

**ANSWER:** Denied.

26. On information and belief, the ANDA Products are generic versions of ARI's Selenious Acid Products ((1) eq. 600 mcg Selenium/10mL (eq. 60 mcg Selenium/mL) and (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL)), as their reference listed drug, containing the same or equivalent ingredients in the same or equivalent amounts.

**ANSWER:** Accord admits that the ANDA Products are Selenious Acid Injection USP, 60 mcg base/mL single-dose vials; 600 mcg base/10 mL (60 mcg base/mL) Pharmacy Bulk Package and that ARI's Selenious Acid Products ((1) eq. 600 mcg Selenium/10mL (eq. 60 mcg Selenium/mL) and (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL)) are their referenced listed drug. Accord lacks information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 26, and therefore denies them.

**ANSWER:**

27. In the Notice Letter, Accord disclosed that the ANDA Products are: Selenious Acid Injection USP, 60 mcg base/mL single-dose vials and 600 mcg base/10 mL (60 mcg base/mL) Pharmacy Bulk Package. On information and belief, the ANDA Products contain the same or equivalent ingredients in the same or equivalent amounts as ARI's Selenious Acid products ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL) and (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL)).

**ANSWER:** Accord admits that the ANDA Products are Selenious Acid Injection USP, 60 mcg base/mL single-dose vials and 600 mcg base/10 mL (60 mcg base/mL) Pharmacy Bulk Package. Accord lacks information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 27, and therefore denies them.



28. On information and belief, the ANDA Products will feature the same or equivalent chemical and therapeutic properties as ARI's Selenious Acid products.

**ANSWER:** Accord lacks information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 28, and therefore denies them.

**COUNT I: INFRINGEMENT OF THE '565 PATENT**

29. ARI realleges paragraphs 1-28 as if fully set forth herein.

**ANSWER:** Insofar as Plaintiff incorporates the allegations of the proceeding paragraphs 1-28 of the Complaint, Accord repeats and realleges its responses thereto, as if fully set forth herein.

30. Accord's submissions of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Products in or into the United States, prior to the expiration of the '565 patent, constitutes direct and indirect infringement of the '565 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

31. On information and belief, the ANDA Products, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Accord or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '565 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Products will occur with Accord's specific intent and encouragement, and will constitute conduct that Accord knows or should know will occur. On information and belief, Accord will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '565 patent.

**ANSWER:** Denied.

32. On information and belief, Accord's manufacture, use, offer for sale, sale, and/or importation of the ANDA Products, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and/or contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '565 patent, either literally or under the doctrine of equivalents. On information and belief, Accord intends that the ANDA Products be used by patients and medical professionals. Also, on information and belief, Accord knows that the ANDA Products are especially made or

adapted for use in infringing the '565 patent, and that the ANDA Products are not suitable for substantial non-infringing use.

**ANSWER:** Denied.

33. ARI will be irreparably harmed if Accord is permitted to make, use, sell, offer to sell, and/or import the ANDA Products in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '565 patent, or any later expiration of exclusivity for the '565 patent to which ARI is or becomes entitled, and in an injunction against such infringement. ARI does not have an adequate remedy at law.

**ANSWER:** Denied.

34. Accord has knowledge of the '565 patent since at least the date Accord submitted the ANDA with a Paragraph IV Certification and was aware that submission of the ANDA with a Paragraph IV Certification constituted an act of infringement under 35 U.S.C. § 271(e)(2).

**ANSWER:** Paragraph 34 contains legal conclusions to which no response is required. To the extent a response is required, Accord admits that it has been aware of the '565 patent since at least the date on which Accord submitted its Paragraph IV Certification. Accord denies the remaining allegations in Paragraph 34.

35. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

**ANSWER:** Denied.

### **PRAYER FOR RELIEF**

Accord denies that Plaintiff is entitled to any of the relief requested against Accord in Paragraphs (a) through (h) of the Prayer for Relief section of the Complaint.

### **GENERAL DENIAL**

To the extent not specifically admitted above, including but not limited to every instance where Accord is without knowledge or information sufficient to form a belief about the truth of the allegations, Accord denies all allegations of the Complaint, including all headings to the extent the headings may be deemed allegations.

### **AFFIRMATIVE AND OTHER DEFENSES**

In response to Plaintiff's Complaint, Accord asserts the following affirmative and other defenses. In asserting these defenses, Accord does not assume the burden of proof with respect to any issue upon which applicable law puts the burden of proof upon Plaintiff.

#### **First Affirmative Defense** **Failure to State a Claim**

Plaintiff's Complaint, in whole or in part, fails to state a claim upon which relief may be granted.

#### **Second Affirmative Defense** **Non-Infringement of the '565 Patent**

The submission of ANDA No. 218655 to FDA did not, and the importation, manufacture, use, offer for sale, or sale of the Proposed ANDA Products will not, infringe any valid and enforceable claim of the '565 patent under any section of 35 U.S.C. § 271, either literally or under the doctrine of equivalents.

#### **Third Affirmative Defense** **Invalidity of the '565 Patent**

The claims of the '565 patent are invalid for failure to satisfy one or more of the conditions for patentability of 35 U.S.C. § 101 *et seq.*

#### **Fourth Affirmative Defense** **No Costs**

Upon information and belief, Plaintiff is barred under 35 U.S.C. § 288 from recovering costs in connection with this action.

#### **Fifth Affirmative Defense** **Failure to State Claim of Willfulness**

Plaintiff fails to state a proper claim for willful infringement or exceptional case under 35 U.S.C. §§ 271(e)(4) and 285, or otherwise.

### **RESERVATION OF DEFENSES**

Accord reserves the right to assert additional defenses in the event that discovery or other analysis indicates that additional separate and/or affirmative defenses are appropriate, including, but not limited to, the defense of unenforceability.

### **COUNTERCLAIMS**

For its counterclaims against American Regent, Inc. (“Counterclaim Defendant”), Accord Healthcare Inc. (“Counterclaimant Accord”) states as follows:

#### **The Parties**

1. Accord Healthcare Inc. is a corporation organized and existing under the laws of North Carolina, having a principal place of business at 8041 Arco Corporate Drive, Suite 200, Raleigh, NC 27617.

2. On information and belief, based on Counterclaim Defendant’s allegation, American Regent, Inc. is a corporation organized and existing under the laws of the State of New York, with its principal place of business at 5 Ramsey Road, Shirley, New York 11967.

#### **Nature of the Action**

3. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

4. Counterclaimant Accord seeks a declaration that it has not infringed, is not infringing, or will not infringe, directly or indirectly, any valid and enforceable claim of United States Patent No. 11,998,565 (“the ’565 patent”), literally or under the doctrine of equivalents.

5. Counterclaimant Accord also seeks a declaration that the claims of the ’565 patent are invalid under one or more sections of 35 U.S.C. § 101 *et seq.*

6. As a consequence of Counterclaim Defendant's Complaint against Counterclaimant Accord, and based on Accord's denials in its Answer, there exists an actual, continuing, and substantial case or controversy between Counterclaim Defendant and Counterclaimant Accord having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the alleged infringement of the '565 patent.

### **Jurisdiction and Venue**

7. This Court has subject matter jurisdiction over these Counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Counterclaim Defendant has submitted to this Court's personal jurisdiction by suing Counterclaimant Accord in this District. On information and belief, Counterclaim Defendant sells products in this District, including the Selenious Acid products at issue in this case, and conducts substantial business in, and has regular and systemic contacts with, this District.

9. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

### **Background**

10. American Regent, Inc. is the holder of New Drug Application ("NDA") No. 209379 for Selenious Acid injection vials.

11. The '565 patent is listed in the Orange Book for Selenious Acid.

12. The face of the '565 patent, titled "Trace Element Compositions, Methods of Making and Use," states that it issued on June 4, 2023.

13. Based on the face of the '565 patent, and on information and belief, American Regent, Inc. is the assignee of the '565 patent.

14. Accord Healthcare Inc. submitted ANDA No. 2186555 to FDA seeking approval for Selenious Acid Injection USP, 60 mcg base/mL single-dose vials; 600 mcg base/10 mL (60 mcg base/mL) Pharmacy Bulk Package (“Proposed ANDA Products”).

15. By a letter dated June 11, 2024 (“Notice Letter”), Counterclaimant Accord notified Counterclaim Defendant of the filing of ANDA No. 219430 and that the filing contains a certification provided for in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that each claim of the ’565 patent is invalid, unenforceable, and/or will not be infringed by the Proposed ANDA Products.

16. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), the Notice Letter included a detailed statement of the factual and legal basis for the certification that each claim of the ’565 patent is invalid, unenforceable, and/or will not be infringed by the Proposed ANDA Products.

17. Counterclaim Defendant filed suit on July 16, 2024, alleging that Counterclaimant Accord infringed the ’565 patent.

**First Counterclaim**  
**Declaratory Judgment of Non-Infringement of the ’565 Patent**

18. Counterclaimant Accord realleges Paragraphs 1-17 as if fully set forth herein.

19. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Accord and Counterclaim Defendant regarding non-infringement of the ’565 patent.

20. Counterclaim Defendant has accused Counterclaimant Accord of infringing the ’565 patent in connection with submission of ANDA No. 218655 and in connection with the prospective manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products if ANDA No. 218655 is approved.

21. The submission of ANDA No. 218655 to FDA does not infringe, directly or indirectly, any valid and enforceable claim of the '565 patent, either literally or under the doctrine of equivalents.

22. The manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Products pursuant to ANDA No. 218655 would not infringe, directly or indirectly, any valid and enforceable claim of the '565 patent, either literally or under the doctrine of equivalents.

23. Because Counterclaimant Accord has not infringed and will not infringe any valid and enforceable claim of the '565 patent, Counterclaim Defendant is not entitled to any damages or any other relief from or against Counterclaimant Accord.

24. Counterclaimant Accord is entitled to a declaration that the submission of ANDA No. 218655 to FDA does not infringe any valid and enforceable claim of the '565 patent.

25. Further, Counterclaimant Accord is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Proposed ANDA Products have not infringed, do not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '565 patent.

**Second Counterclaim**  
**Declaratory Judgment of Invalidity of the '565 Patent**

26. Counterclaimant Accord realleges Paragraphs 1-25 as if fully set forth herein.

27. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaimant Accord and Counterclaim Defendant regarding invalidity of the '565 patent.

28. The '565 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101,

102, 103, 112, and/or 116, including for the reasons stated in Accord's Notice Letter and Detailed Statement, and/or for obviousness type double patenting.

29. Counterclaimant Accord is entitled to a judicial declaration that the '565 patent is invalid.

**Prayer for Relief**

WHEREFORE, Counterclaimant Accord respectfully requests that the Court award the following relief:

A. A declaration that by filing ANDA No. 218655, Counterclaimant Accord has not infringed, is not infringing, and will not infringe, directly or indirectly, any valid and enforceable claim of the '565 patent, literally or under the doctrine of equivalents, and that Counterclaimant Accord has a lawful right to obtain FDA approval of its ANDA No. 218655 for selenious acid injection vials;

B. A declaration that Counterclaimant Accord will not directly infringe, or contribute to or induce infringement of any valid and enforceable claim of the '565 patent, literally or under the doctrine of equivalents, by the importation, manufacture, use, offer for sale, or sale of the selenious acid injection vials that are the subject of ANDA No. 218655;

C. A declaration that the '565 patent is invalid;

D. An injunction against Counterclaim Defendant, their officers, employees, agents, representatives, attorneys, and others acting on their behalf, from threatening or initiating infringement litigation against Counterclaimant Accord or its customers, suppliers, or any prospective or present sellers, distributors, or customers of Counterclaimant Accord, or charging them either verbally or in writing with infringement of the '565 patent with respect to the selenious acid injection vials that are the subject of ANDA No. 218655;



E. A declaration that this is an exceptional case, and that the Counterclaimant Accord be awarded its attorneys' fees and costs pursuant to 35 U.S.C. § 285;

F. A declaration that Counterclaim Defendant is entitled to no damages, interest, costs, or other relief (including injunctive relief) from or against Counterclaimant Accord for infringement of the '565 patent;

G. An award of costs and expenses to Counterclaimant Accord; and

H. An award to Counterclaimant Accord of such further relief as this Court may deem necessary, just, and proper.

Dated: August 15, 2024

**BENESCH FRIEDLANDER COPLAN  
& ARONOFF LLP**

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*Attorneys for Defendant Accord Healthcare Inc.*

**CERTIFICATE OF SERVICE**

I hereby certify that on August 15, 2024, a copy of the foregoing *Defendant Accord Healthcare Inc.'s Answer to Plaintiffs' Complaint with Affirmative Defenses and Counterclaims* was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. Parties may access this filing through the Court's CM/ECF system.

/s/ Kristen Healey Cramer  
Kristen Healey Cramer

*Attorney for Defendant Accord Healthcare Inc.*